

CERTIFICATE OF ANALYSIS

(Certificate No. KML012006-01)

Release Date: 28/01/2023

Re-test Date: 27/01/2026

Leflunomide EP Impurity A

Identification

Chemical Name :

4-(Trifluoromethyl)aniline

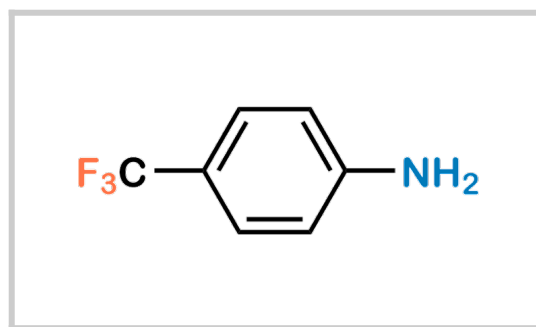
Alt. Name : Leflunomide USP Related Compound A

CAT No. : KML012006

CAS No. : 455-14-1

Molecular Formula : C₇H₆F₃N

Molecular Weight : 161.1



Analytical Information

Batch No. : LEF-EP-A-045-017

Solubility : Acetonitrile

Description : Colorless Syrup

Mass : Confirm

HPLC Purity : 99.94 %

IR : Confirm

Weight Loss By TGA : 1.96 %

¹H NMR : Confirm

% Potency : 97.98 %

¹³C NMR : Confirm

Additional Information

Long Term Storage : Store at 2-8 deg. C for long term storage

Shipping Condition : Product is stable to be Shipped at Room Temperature

% Potency = [100 - 1.96(Weight Loss By TGA)] x [99.94(HPLC Purity)]/100 = 97.98 %

Remarks : COA Re-generated on 27.11.2024

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		27/11/2024
Reviewed & Approved By	Quality Control	Jatin Patel		27/11/2024

Attachments : COA, HPLC, MASS, ¹H NMR, ¹³C NMR, IR and TGA